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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,101	04/19/2004	Julius G. Hammerslag	HEMOSTA.022C1	1451
20995	7590	12/15/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/827,101		HAMMERSLAG, JULIUS G.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Anu Ramana		3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/6/2004</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 18 is objected to because of the following informalities. It appears that claim 18 should depend from claim 12 instead of claim 11 as stated. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 12-15, 25-28 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandarin (US 3,030,951).

Mandarin discloses posterior and anterior spinal fusion by injecting a polyurethane polymer that polymerizes or “undergoes a chemical transformation” to cement the bony surfaces of adjacent vertebrae (Fig. 4, col. 1, lines 64-72, col. 2, lines 62-72 and col. 3, lines 8-24).

The claimed method steps are inherently performed when a medium is injected between adjacent vertebrae as disclosed by Mandarin.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2, 9-10 and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarin (US 3,030,951), as applied to claim 1, in view of Scribner et al. (US 2002/0099384).

Mandarin discloses all elements of the claimed invention except for performing the procedure in a minimally invasive manner.

Scribner et al. teach treatment of vertebral bodies from many different directions in a minimally invasive manner depending on the complexity of the procedure (para [0047]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed vertebral joint repair utilizing an approach that is minimally invasive, as taught by Scribner et al. depending on the complexity of the procedure.

Claims 4, 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarin (US 3,030,951), as applied to claim 1, in view of Boucher et al. (US 6,716,216).

Mandarin discloses all elements of the claimed invention except for use of cyanoacrylate.

Boucher et al. teaches the use of polyurethanes or cyanoacrylates for treating vertebral bodies (col. 7, lines 15-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized cyanoacrylates instead of polyurethanes for intervertebral stabilization, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 3, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarin (US 3,030,951) in view of Preissmann (US 6,309,420).

Mandarin discloses all elements of the claimed invention except for performing the procedure with radiographic visualization.

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Preissman teaches the use of radiographic contrast agents in bone cements for viewing injection of bone cement or "medium" into a bone (col. 1, lines 56-69, col. 2, lines 36-37 and col. 4, lines 8-16).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized fluoroscopic visualization, as taught by Preissman, in the method of fixing a vertebral joint disclosed by Mandarino, to enable viewing of the path taken by the injected medium.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-20, 22-29 and 31-33 ('claims of the present application') are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, 9, 11, 14 and 15 of U.S. Patent No. 6,723,095 ("patented claims" herein). Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between claims 25-29 and 31-33 of the present application and the patented claims is that the patented claims are more specific. Thus the invention of the patented claims in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d

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2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the patented claims they are not patentably distinct from the patented claims.

Claims 3 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,723,095 ('095 herein) in view of Preissman (US 6,309,420).

Claim 6 of '095 discloses all the method steps except for radiographic visualization.

Preissman teaches the use of radiographic contrast agents in bone cements for viewing injection of bone cement or "medium" (col. 1, lines 56-69, col. 2, lines 36-37 and col. 4, lines 8-16).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized fluoroscopic visualization, as taught by Preissman, in the method of claim 6 of '095 to enable viewing of the path taken by the injected medium.

Claim 30 rejected under 35 U.S.C. 103(a) as being unpatentable over patented claim 6, in view of Scribner et al. (US 2002/0099384).

Patented claim 6 discloses all elements of the claimed invention except for performing the procedure in a minimally invasive manner.

Scribner et al. teach treatment of vertebral bodies from many different directions in a minimally invasive manner depending on the complexity of the procedure (para [0047]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed vertebral joint repair utilizing an approach that is minimally invasive, as taught by Scribner et al. depending on the complexity of the procedure.

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### ***Conclusion***


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*  
December 13, 2004

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER